IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re: Rosuvastatin Calcium Patent Litigation	Civ. No. 08-md-1949 **REDACTED VERSION OF DI 443**
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Mylan Pharmaceuticals Inc., Defendant.	Civ. No. 07-805-JJF-LPS **REDACTED VERSION OF DI 213**
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Sun Pharmaceutical Industries, Ltd., Defendant.	Civ. No. 07-806-JJF-LPS **REDACTED VERSION OF DI 216**
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Sandoz, Inc., Defendant.	Civ. No. 07-807-JJF-LPS **REDACTED VERSION OF DI 232**

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Par Pharmaceutical, Inc., Defendant.	Civ. No. 07-808-JJF-LPS **REDACTED VERSION OF DI 209**
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Apotex Inc. and Apotex Corp., Defendants.	Civ. No. 07-809-JJF-LPS **REDACTED VERSION OF DI 248**
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc., Defendants.	Civ. No. 07-810-JJF-LPS **REDACTED VERSION OF DI 329**
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc., Defendants.	Civ. No. 07-811-JJF-LPS **REDACTED VERSION OF DI 261**

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Aurobindo Pharma USA Inc. and Aurobindo Pharma Limited Inc., Defendants.	Civ. No. 08-359-JJF-LPS **REDACTED VERSION OF DI 193**
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha, Plaintiffs, v. Teva Pharmaceuticals USA, Inc., Defendant.	Civ. No. 08-426-JJF-LPS **REDACTED VERSION OF DI 197**

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS ASTRAZENECA PHARMACEUTICALS LP FOR LACK OF STANDING

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PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS ASTRAZENECA PHARMACEUTICALS LP FOR LACK OF STANDING

Plaintiffs Shionogi Seiyaku Kabushiki Kaisha ("Shionogi"), AstraZeneca UK Ltd. ("AZ UK"), IPR Pharmaceuticals Inc. ("IPR") and AstraZeneca Pharmaceuticals LP ("AZ PLP") oppose the motion by Defendants to dismiss one of the Plaintiffs, AZ PLP, for alleged lack of standing to sue Defendants. (D.I. No. 422).[1] Defendants do not dispute standing for the three other Plaintiffs or suggest that this case is not properly before this Court, and first raised this standing issue regarding AZ PLP just a few weeks ago.

AZ PLP has standing to join as a party-plaintiff, because AZ PLP serves as the exclusive agent IPR, of the owner of the New Drug Application ("NDA") for Crestor®, and in that role submitted IPR's NDA to the FDA. [redacted] That, coupled with the fact that AZ PLP is IPR's licensed marketer of Crestor® in the United States, gives AZ PLP sufficient interest in these disputes under the Hatch-Waxman Act to be a co-plaintiff in these actions along with the patent owner (Shionogi), exclusive licensee (AZ UK) and exclusive sub-licensee/NDA holder (IPR).

Defendants' motion involves a narrow question of law that raises an issue of first impression: whether the exclusive agent of an NDA holder has standing to join

[1] "D.I. No. __" refers to the docket index number for the consolidated *In re Rosuvastatin* cases, No. 08-md-1949-JJF-LPS.

the patent owner and the NDA holder to sue for patent infringement under the Hatch-Waxman Act. The Hatch-Waxman Act provides an independent basis for NDA holders and their agents to have standing in patent infringement cases brought under the Act, as shown by the text and structure of the Act, as well as congressional intent.

I. Facts

Plaintiffs brought these Hatch-Waxman Act[2] patent infringement actions in response to Defendants' Paragraph IV notifications that they applied for approval to market generic versions of AstraZeneca's Crestor® rosuvastatin calcium product and challenged the patent protecting Crestor®. Specifically, they filed Abbreviated New Drug Applications ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to market generic copies of Crestor® prior to the expiration of Plaintiff Shionogi's U.S. Patent No. Re 37,314 ("the '314 patent"). Filing such an ANDA is an act of patent infringement. 35 U.S.C. § 271(e)(2)(A).

In response to those filings and Paragraph IV certifications, the following four Plaintiffs sued Defendants for infringing the '314 patent:

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[2] The Hatch-Waxman Act is formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at, *inter alia*, 21 U.S.C. § 355 and 35 U.S.C. § 271(e), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003)("MMA"). ANDA litigation and the Hatch-Waxman Act have been described in, *e.g.*, *Dey, L.P. v. Sepracor, Inc.* 595 F. Supp. 2d 355, 356-57 (D. Del. 2009) (Farnan, J.); *see also Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1325-27 (Fed. Cir. 2001).

- Shionogi, a Japanese corporation, owns the '314 patent by assignment from the inventors. (Bourke Decl. Exh. 17).[3]
- AZ UK, a UK corporation, is the successor in interest to the former Zeneca, Ltd. and Shionogi's exclusive licensee under the '314 patent. (Bourke Decl. Exh. 1).
- IPR, a Puerto Rico corporation and wholly-owned subsidary of AZ UK, is AZ UK's exclusive sub-licensee under the '314 patent. (Bourke Decl. Exhs. 1, 16). IPR also holds New Drug Application ("NDA") No. 021366, which the FDA approved for Crestor®, the rosuvastatin calcium product Defendants seek to copy. (Bourke Decl. Exhs. 11, 12).
- AZ PLP, a Delaware corporation, serves as IPR's sole authorized agent before the FDA for the Crestor® NDA. (Bourke Decl. Exh. 13, 14). In that role, AZ PLP submitted and signed that NDA and is responsible for all matters related to that NDA. (Bourke Decl. Exh. 13). [redacted] (Bourke Decl. Exhs. 15, 16). [redacted]

[3] The citations herein to "Bourke Decl. Exh. __" refer to the exhibits appended to the accompanying Declaration of Mary W. Bourke.

[redacted]

II. Discussion

This case arises under both the patent laws and the Hatch-Waxman Act and therefore substantially differs from most patent cases. If this were a typical patent case, AZ PLP would lack standing because it holds no exclusive right in the patent in suit. But this is not a typical patent case. This is a Hatch-Waxman Act patent infringement case. The tight interrelationship between the patentee and NDA holder in Hatch-Waxman Act patent infringement cases endows the NDA holder and its agent with standing to sue in an infringement action brought under the Act, independent of whatever rights they may have in the patent, when joined as co-plaintiffs with the patentee.

A. Standing in Patent Cases

Standing relates to the ability of an individual to be a party to litigation. At a minimum, for standing to exist, Article III of the Constitution requires that a party demonstrate: (1) an injury in fact, (2) with a fairly traceable connection to the challenged action, and (3) the requested relief will redress the alleged injury. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 (1998). The courts also recognize three additional

standing requirements: (1) a party generally must litigate its own right and not a third party's rights, (2) the question must not be an abstract, generalized grievance, and (3) the harm must be in the zone of interests protected by the relevant statute or constitutional provision. *Valley Forge Christian College v. Americans United for Separation of Church & State*, 454 U.S. 464, 474-75 (1982).

Plaintiffs in patent cases fall into three categories: "[1] those that can sue in their own name alone; [2] those that can sue as long as the patent owner is joined in the suit; and [3] those that cannot even participate as a party to an infringement suit." *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1339 (Fed. Cir. 2007).

Ordinarily, the first category includes plaintiffs who hold all rights in the patent, such as assignees and exclusive licensees to whom have been transferred all substantial rights in a patent. Likewise, ordinarily, the second category includes exclusive licensees who have received some, but not all, substantial rights in the patent. The third category includes mere nonexclusive licensees.

B. The Hatch-Waxman Act Provides Standing for NDA Holders Independent of Patent Rights

NDA holders fall within the second category of *Morrow* in the case of a Hatch-Waxman Act infringement case, based on the text, structure, and legislative history of the Act.

The Hatch-Waxman Act supports standing for NDA holders. Importantly, ANDA filers piggyback off the proprietary safety and efficacy data submitted by the NDA holder for the approved drug. 21 U.S.C. § 355(j)(2)(A). Without the studies submitted with the NDA, there would be no ANDA. In addition, NDA holders have the statutory obligation to inform the FDA of a patent that covers the NDA drug and that

eventually forms the basis of Hatch-Waxman Act patent litigation. *Id.* at § 355(b)(1). NDA holders also have the right, together with the patentee, to receive a Notice Letter from Paragraph IV ANDA-filing generic drug companies. *Id.* at § 355(j)(2)(B)(iii).

Quite significantly, the 2003 amendments to the Hatch-Waxman Act, intended to level the playing field between branded and generic drug companies, strongly suggesting that NDA holders were intended to participate in this kind of patent litigation. The amendments permit a generic drug company to maintain a declaratory judgment action for patent certainty against the NDA holder and a counterclaim to order the NDA holder to remove Orange Book listed patents. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I) and (II) (declaratory judgment action); 35 U.S.C. § 271(e)(5) (declaratory judgment action); 21 U.S.C. § 355(j)(5)(C)(ii)(delisting action).

1. <u>The Hatch-Waxman Act Structure and Text Support Standing</u>

Originally adopted in 1984, the Hatch-Waxman Act created a unique form of patent litigation. The Act permits, in specified circumstances, the filing of an ANDA to obtain FDA approval of a drug previously approved by the FDA. *See, e.g., Yamamouchi Pharm. Co. v. Danbury Pharm., Inc.*, 231 F.3d 1339, 1342 (Fed. Cir. 2000). It allows the FDA review process for generic drugs to proceed in parallel with patent infringement litigation.

The Hatch-Waxman Act system works as follows: The innovator company (*e.g.*, AstraZeneca) files an NDA, "frequently a time-intensive and costly process, because among other things, it must contain detailed clinical studies of the drug's safety and efficacy." *Mylan*, 268 F.3d at 1325. The NDA applicant must identify patents for which "infringement could reasonably be asserted" due to the unlicensed "manufacture, use or sale of the drug" – regardless of whether the NDA applicant owns the patent or is

licensed by the patentee. The NDA applicant then provides to the FDA the patent number and expiration date of any such patent. *See* 21 U.S.C. § 355(b)(1).

The FDA lists this information in its *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly called the "Orange Book." 21 U.S.C. §§ 355(b)(1) and (j)(7)(A)(iii).

Abbreviated NDA applicants (*e.g.*, the Defendants here) do not have to undertake the time-intensive and costly studies underlying an NDA. Instead, they "piggyback" off the innovator company's previously-submitted safety and efficacy data for the NDA product (called "the listed drug"). ANDA applicants merely must show that the ANDA product is "bioequivalent" to the innovator's NDA-approved drug. 21 U.S.C. § 355(j)(2)(A)(iv). *See also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1362 (Fed. Cir. 2003).

An ANDA must include one of two certifications regarding each unexpired Orange Book-listed patent the NDA holder identified to the FDA. Specifically, the ANDA applicant must certify either that the patent covering the approved drug will expire on a specified date (in which case the FDA will not allow approval of the generic drug until after that date), or that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug" covered by the ANDA. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III)-(IV). The latter type of certification is known as a "Paragraph IV" certification and it means that the generic drug company seeks immediate approval to market its drug notwithstanding the existence of the unexpired listed patent.

Particularly important to the present issue, an ANDA applicant certifying under Paragraph IV must provide to *both* the patent owner *and* the NDA holder a

"detailed statement of the factual and legal basis of the opinion of the [generic] applicant that the patent is invalid or will not be infringed." *Id.* at § 355(j)(2)(B)(iii) and (iv)(II).

Filing an ANDA with a Paragraph IV certification is a technical act of patent infringement under 35 U.S.C. § 271(e)(2). Receipt of the Notice Letter triggers the right to bring an infringement action under the Hatch-Waxman Act. If the action is brought within 45 days of receipt of the Notice Letter, FDA approval of the ANDA is automatically stayed for 30 months (called "a 30 month stay"). 21 U.S.C. § 355(j)(5)(B)(iii). The ANDA filer may not seek declaratory relief during that 45-day period. *Id.* at § 355(j)(5)(C)(i)(I).

2. The 2003 Amendments to the Hatch-Waxman Act Indicate Standing

In 2003, the MMA amended the Hatch-Waxman Act in ways that support an NDA holder's and its agent's participation in infringement actions brought under the Act. Prior to 2003, ANDA filers frequently found it difficult to obtain certainty about future rights to market ANDA products if they were not sued within 45 days. Although generic drug companies had the theoretical right to seek declaratory relief, ANDA filers frequently could not establish a "case or controversy" for technical reasons. Similarly, a generic drug applicant had no means to challenge directly whether the NDA holder had properly listed patents in the Orange Book. Courts refused to recognize a direct cause of action by generic drug companies seeking an order requiring the NDA holder to remove ("delist") patents from the Orange Book. *Mylan*, 268 F.3d at 1332.

The MMA amended the Hatch-Waxman Act to redress these issues. Under the MMA, once the 45-day period has expired and if "neither" the patent owner "*nor the [NDA-]holder*" has brought an infringement action, the ANDA filer who

provided a Paragraph IV certification may bring an action "against the [patent] owner *or [NDA-]holder*" for a declaratory judgment that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(5)(C)(i)(I) and (II) (emphasis added). In addition, under the MMA, if the patent owner "*or the [NDA-]holder*" brings an action against the ANDA filer, the ANDA filer may assert a counterclaim seeking an order "requiring *the [NDA] holder*" to correct or delete the patent information listed in the Orange Book. *Id.* at § 355(j)(5)(C)(ii)(I) (emphasis added).

Congress intended the declaratory judgment action to "level the playing field" by giving ANDA-filers the same rights as the NDA holder and patentee to initiate litigation after the passage of 45 days. In doing so, Congress indicated that the Hatch-Waxman Act permitted *both* the patentee and the NDA holder to bring an infringement suit, even under the pre-2003 Act. For example, Senator Edward M. Kennedy stated:

> It's worth pointing out that the Hatch-Waxman Act has always provided *that patent owners and brand drug companies* can bring patent infringement suits against a generic applicant immediately upon receiving notice that the generic applicant is challenging a patent. The declaratory judgment provisions in Title XI of this bill simply level the playing field by making it clear that the generic applicant can also seek a prompt resolution of these patent issues by bringing a declaratory judgment action if *neither the patent owner nor the brand drug company* brings such a suit within 45 days after receiving notice of the patent challenge.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy) (emphasis added).

Consequently, the declaratory judgment provisions explicitly authorize a civil action against the patentee and the NDA holder for a declaratory judgment of patent invalidity or noninfringement. The statutory text plainly implies the complement, that NDA holders may sue during the 45-day window (as Plaintiffs have done here). When

45 days pass "and neither the owner of the patent that is the subject of the certification nor the *holder of the [NDA]*" has sued the generic drug company, federal courts have "subject matter jurisdiction in any action brought by such person under [the Declaratory Judgment Act] for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (emphasis added).

The delisting counterclaim action also strongly suggests that Congress intended NDA holders to be parties to Hatch-Waxman Act litigation. Under this provision, an ANDA filer sued for infringement may file a counterclaim requesting delisting of patents wrongfully listed in the Orange Book:

> If an owner of the [listed] patent *or the holder of the . . . [NDA]* . . . brings a patent infringement action against the [ANDA] applicant, the applicant may assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the holder [of the NDA] . . . that the patent does not claim either—(aa) the drug for which the application was approved; or (bb) an approved method of using the drug.

21 U.S.C. § 355(j)(5)(C)(ii) (emphasis added). No affirmative cause of action exists for delisting. *Id.* at § 355(j)(5)(C)(ii)(II). If the NDA holder were not a party to the *infringement* litigation, this delisting "counterclaim" would provide no relief. The statutory language cannot be meaningless; it must presume that NDA holders have standing to sue for infringement with the patent owner. Otherwise, an NDA applicant's right to this remedy is illusory. The Court should not presume Congress provided a remedy but no ability for ANDA filers to obtain that remedy. "[S]tatutory construction that causes absurd results is to be avoided if at all possible." *Timex V.I. v. United States*, 157 F.3d 879, 886 (Fed. Cir. 1998), *citing Haggar Co. v. Helvering*, 308 U.S. 389, 394

(1940); *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 68-69 (1994); *Green v. Bock Laundry Mach. Co.*, 490 U.S. 504, 527-29 (1989) (Scalia, J., concurring).

The declaratory judgment action and counterclaims added in the MMA thus strongly suggest that an NDA holder has standing to sue as a plaintiff in an infringement action brought under the Act. Congress clearly recognized that the NDA holder and the patentee may be different entities, yet authorized a declaratory judgment action for patent certainty against both – irrespective of whether, or to what extent, the NDA holder has rights in the patent. Conversely, Congress indicated that an NDA holder may sue for infringement with the patentee within 45 days following receipt of the Notice Letter.

C. As the NDA Holder's Exclusive FDA Agent, AZ PLP Has Standing

Defendants argue that AZ PLP lacks standing to sue for infringement, because it has no exclusive rights in the '314 patent. Defendants' arguments miss the mark: the Hatch-Waxman Act provides AZ PLP standing to sue with the patent owner independent of any rights in the '314 patent, as the NDA holder's exclusive FDA agent.

IPR has suffered an injury-in-fact from Defendants' Paragraph IV-certified ANDAs and therefore has standing both as the exclusive sublicensee of the `314 and as the NDA holder.[4] Aside from the patent injury, IPR will suffer injury to its exclusive use of the data underlying the Crestor® NDA and will suffer economic injury from sales of generic rosuvastatin calcium products if Defendants' ANDAs are approved. These injuries are clearly traceable to the actions of Defendants and will be remedied by

[4] Defendants do not dispute IPR's standing.

the relief sought – an order prohibiting the FDA from approving Defendants' ANDAs prior to the expiration of the '314 patent.

AZ PLP is similarly injured, both from sharing in IPR's injury as its agent and based on independent harm to itself. AZ PLP, as IPR's exclusive agent, submitted the NDA for Crestor® and is substantively responsible for communicating with the FDA regarding that NDA. [redacted] AZ PLP effectively stands in the shoes of IPR for all purposes related to the Crestor® NDA

The law of agency further supports AZ PLP's standing here. An agent may bring an action in its own name for a tort committed by a third party against the principal, if the third party's actions were intended "for the purpose of harming the agent's interests." Restatement (2d) of Agency § 374(2) (1957). Here, Defendants' ANDA filings necessarily were intended to, and did, harm AZ PLP's interests both in the NDA and in its marketing of Crestor [redacted]

AZ PLP also will suffer economic injury if Defendants' generic rosuvastatin calcium products are permitted on the market prior to the expiration of the '314 patent. Although, as Defendants note, AZ PLP recently engaged Abbott

Pharmaceuticals to assist in providing marketing services, AZ PLP is still ultimately responsible to IPR for marketing Crestor®. *See* Def's Exh. F.[5]

AZ PLP therefore has standing to be a co-plaintiff in this case.

III. Conclusion

For the foregoing reasons, Plaintiff AZ PLP has standing to sue Defendants for infringement of the '314 patent in a suit along with the patent owner. Accordingly, the Court should deny Defendants' Motion to Dismiss AstraZeneca Pharmaceuticals LP for Lack of Standing.

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[5] "Def's Exh. __" refers to exhibits attached to the Declaration of Aaron M. Johnson, Esq. submitted with Defendants' opening memorandum. When Plaintiffs brought suit in 2007, AZ PLP was the sole marker and distributor of Crestor® in the United States. In 2008, AZ PLP engaged Abbott to assist it by providing additional marketing services for Crestor®. Under the agreement, Abbott was engaged on a non-exclusive basis to provide marketing services for AZ PLP, primarily in the form of sales calls (called "Details" or "PDEs"). *See id* at AZ01507142-143, ¶ 3.2. AZ PLP retained the right to promote Crestor® in any manner it chooses. *See id* at AZ01507141, ¶ 2.1. Development of marketing materials is AZ PLP's sole responsibility. *See id* at AZ01507144-145, ¶ 3.6.

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